

REMARKS

Claims 1-28 and 30-50 are pending in this application. By this Amendment, claims 27, 30-32 and 34 are amended and claims 40-50 are added. Support for the amendments to the claims may be found, for example, in the specification at page 13, lines 5-11, page 28, lines 6-13, and page 33, line 25 to page 34, line 20, and in the claims as originally filed. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Telephone Interview

The courtesies extended to Applicants' representative by Examiner Whisenant during the telephone interview held March 26, 2010, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

II. Enablement Rejection Under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 1-28 and 30-39 under 35 U.S.C. §112, first paragraph, as not being enabled for their full scope. Applicants respectfully traverse the rejection.

The Office Action asserts that the specification does not provide evidence for the use of compounds able to undergo a specific base pairing interaction at "high" concentrations, such as concentrations above 25 g/l. See page 3. The Office Action asserts that Example 3 of the specification only discloses using base pairing compounds at a combined concentration of 7.5 g/l. Id.

However, as discussed and agreed upon during the interview, the Office Action's assertion with respect to Example 3 of the specification is incorrect because the Office Action

inadvertently refers to concentrations reported in "g/100 ml" as being in "g/l." Instead, Example 3 discloses thymidine or cytidine (the base pairing compounds) at a concentration of 5 g/100 ml, which is a concentration of 50 g/l. In Example 3, when both thymidine and cytidine are present, then one is present at 5 g/100 ml and the other is present at 2.5g/100 ml, for a total concentration of 75 g/l--not 7.5 g/l as mistakenly stated by the Office Action. See page 33, line 25 to page 34, line 20. Thus, Example 3 establishes that the claims are enabled at much higher concentrations than 7.5 g/l.

In fact, the concentration of a base pairing compound is only limited in practice by its solubility. Thus, the claims are enabled for their full scope.

For at least these reasons, claims 1-28 and 30-39 meet the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejection Under 35 U.S.C. §102

The Office Action rejects claims 31 and 32 under 35 U.S.C. §102(a) as being anticipated by Fisher BioReagents' "ex CTGene™ PCR Kits" ("Fisher"). Applicants respectfully traverse the rejection.

Claim 31 requires "a DNA fragment having a nucleic acid sequence that is hybridizable to a portion of a gene on which a point mutation(s) has been associated or putatively associated with a disease or an increased predisposition to a disease." As discussed and agreed upon during the interview, Fisher does not disclose such a DNA fragment.

Claim 32 requires "a pair of DNA probes that are molecular beacons." The specification describes molecular beacons as "single-stranded DNA molecules that may form a stem-and-loop structure and possess an internally quenched fluorophore." See specification at page 28, lines 6-13. Fisher does not disclose molecular beacons.

For at least these reasons, Fisher does not anticipate claims 31 and 32. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejections Under 35 U.S.C. §§102/103

A. Ruiz-Martinez

The Office Action rejects claims 27, 28, and 30 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as having been obvious over Ruiz-Martinez et al., "DNA Sequencing by Capillary Electrophoresis with Replaceable Linear Polyacrylamide and Laser-Induced Fluorescence Detection," ("Ruiz-Martinez"). Applicants respectfully traverse the rejection.

Claim 27 requires "a compound able to undergo specific base pairing interaction at a concentration of at least 1 g/l being present in a liquid separating medium that comprises at least one irregular block copolymer at a concentration of at least 1% by weight." As discussed and agreed upon during the interview, Ruiz-Martinez does not disclose an irregular block copolymer. See also Office Action at page 6 (stating that Ruiz-Martinez teaches "capillary electrophoresis using linear polyacrylamide separating medium" (emphasis added)). Additionally, there would not have been any reason or rationale to modify Ruiz-Martinez to use a non-linear polymer because the linear polyacrylamide is an essential component of the DNA sequencing method disclosed by Ruiz-Martinez.

For at least this reason, Ruiz-Martinez does not anticipate and would not have rendered obvious claim 27. Claims 28 and 30 depend from claim 27 and, thus, also are not anticipated and would not have been rendered obvious by Ruiz-Martinez for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Perkin Elmer

The Office Action rejects claims 31 and 32 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as having been obvious over Perkin Elmer Cetus's "GeneAmp™ DNA Amplification Reagent Kit" ("Perkin Elmer"). Applicants respectfully traverse the rejection.

As discussed above, claim 31 requires "a DNA fragment having a nucleic acid sequence that is hybridizable to a portion of a gene on which a point mutation(s) has been associated or putatively associated with a disease or an increased predisposition to a disease." As discussed and agreed upon during the interview, Perkin Elmer does not disclose such a DNA fragment.

Further, Perkin Elmer would not have rendered obvious the claimed composition comprising such a DNA fragment because there would not have been any reason or rationale for an ordinarily skilled artisan to modify an all-purpose PCR kit to have control DNA that is hybridizable to a portion of a gene associated with disease because the sole purpose of the control DNA is simply to show that a given amplification reaction worked under the reaction conditions. The control DNA does not serve any diagnostic purpose and, thus, it would not have been obvious to include DNA having a diagnostic purpose in an all-purpose PCR kit.

As discussed above, claim 32 requires "a pair of DNA probes that are molecular beacons." Perkin Elmer does not disclose molecular beacons. Additionally, there would not have been any reason or rationale to modify the kit disclosed by Perkin Elmer to include molecular beacons because molecular beacons do not serve the same function as the control primers of the Perkin Elmer's kit. The control primers are used to "prime" amplification reactions, whereas molecular beacons are detection probes that are not useful for priming amplification reactions. Accordingly, an ordinarily skilled artisan would not have modified the kit of Perkin Elmer to include molecular beacons.

For at least these reasons, Perkin Elmer does not anticipate and would not have rendered obvious claims 31 and 32. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

C. Ruiz-Martinez and Stratagene Catalog

The Office Action rejects claim 33 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as having been obvious over Ruiz-Martinez in view of Stratagene Catalog (1988), page 39 ("Stratagene"). Applicants respectfully traverse the rejection.

Claim 33 depends from claim 27 and, therefore, contains all the features of claim 27. Deficiencies of Ruiz-Martinez are discussed above with respect to claim 27. Stratagene, which the Office Action applies with respect to additional features recited in claim 33, fails to cure deficiencies of Ruiz-Martinez.

Thus, Ruiz-Martinez does not anticipate and would not have rendered obvious, individually or in combination with Stratagene, claim 33. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 34 and 35 under 35 U.S.C. §103(a) as having been obvious over Saiki et al., "Analysis of Enzymatically Amplified β -globin and HLA-DQ α DNA with Allele-Specific Oligonucleotide Probes" ("Saiki"). Applicants respectfully traverse the rejection.

Claim 34 requires that the base pairing compounds are "unable to be incorporated into a newly polymerized nucleic acid." As discussed and agreed upon during the interview, Saiki only discloses dNTPs that are able to be incorporated in a newly polymerized strand, and does not establish any reason or rationale to use base pairing compounds that are unable to be incorporated into a newly polymerized nucleic acid.

For at least these reasons, Saiki would not have rendered obvious claim 34. Claim 35 depends from claim 34 and, thus, also would not have been rendered obvious by Saiki for at least the same reason. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

VI. New Claims

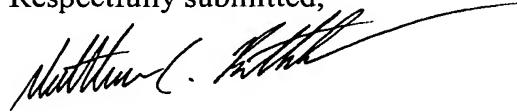
By this Amendment, new claims 40-50 are presented. New Claims 40-50 are dependent claims and, thus, distinguish over the applied references for at least the reasons that the independent claims from which they respectively depend distinguish over the applied references. Claims 40-50 are directed to 75 g/l as the upper concentration limit for the base pairing compounds and, thus, are enabled for their full scope for at least the same reasons as discussed above with respect to claims 1-28 and 30-39. Accordingly, prompt examination and allowance of claims 40-50 are respectfully requested.

VII. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachment:

Amendment Transmittal

Date: March 30, 2010

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